



RESEARCH ARTICLE

EFFECT OF LOW-LEVEL LASER THERAPY VERSUS NEGATIVE PRESSURE WOUND THERAPY ON PRESSURE ULCERS

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ABSTRACT

Background: Pressure ulcers are a potential problem in intensive care patients, their prevention and treatment is a major issue in care. Pressure ulcers are considered to be a largely preventable problem, and yet despite extensive training and the expenditure of a large amount of resources, they persist. **Objective:** This study was designed to investigate the difference in the effect between negative pressure therapy and low level laser therapy on Pressure ulcers healing. **Methods:** Forty-five patients diagnosed with pressure ulcer patients (grade II or III), their ages ranged from 45 to 65 years, were assigned randomly in to three groups of equal number. Group A: received the LLLT treating the ulcer according to the grid technique 90 seconds for every centimeter square of the ulcer surface with 10 minutes as the total time of the session, 3 times per week for 4 weeks and the traditional medical care. Group B: received the Vacuum assisted closure therapy: Initial cycle; continuous mode for first 2 days. Subsequent cycle; intermittent mode (5min. ON: 2min. OFF). With target pressure: -125mmHg, daily for 4 weeks and the traditional medical care. Group C received only the traditional medical care. for 4weeks. Wound surface area and wound volume were assessed by Wound Desk Smart app and sterile gel respectively pretreatment and 4 weeks after treatment. **Results:** There were significant decrease in wound surface area and wound volume in all groups ($p < 0.001$). However higher statistical results were achieved in NPWT group, as wound surface area and volume decreased in NPWT group by 37,24%, and 43,9% respectively while in LLLT group decreased by 21,46% and 33,58% respectively, on the other side the control group exhibits reduction only by 9,45% , and 22,7% respectively. **Conclusion:** Both negative pressure therapy and LLLT have fruitful effects in pressure ulcer healing evidenced by the significant decrease of wound volume and surface area, however higher statistical improvement was reported in the negative pressure therapy.

INTRODUCTION

A pressure ulcer is defined as an area of localized damage to the skin and underlying tissue caused by pressure, shear, or friction, or a combination of these. Pressure ulcers are caused by a local breakdown of soft tissue as a result of compression between a bony prominence and an external surface (Grey, 2006). Pressure ulcer prevalence is used worldwide as a quality indicator, providing a benchmark to evaluate care in various settings. Studies show prevalence in hospital settings ranging between 0 and 46 %. To identify patients at risk for pressure ulcer is a central component of clinical practice (Muntlin Athlin, 2016).

Pressure ulcer treatment involves various approaches, including interventions to treat the conditions that lead to pressure ulcers (support surfaces and nutritional support), interventions to protect and promote healing of the ulcer (wound dressings; topical applications; and various adjunctive therapies, such as electrical stimulation, therapeutic ultrasound, Hyperbaric oxygen therapy, hydrotherapy, light therapy, and laser therapy , and vacuum-assisted devices), and surgical repair of the ulcer (Smith, 2013). Among the methods of non-pharmacological treatment, the American College of Physicians describes, among other adjunctive therapies, the use of light therapy and low-level laser therapy (LLLT). Light therapy consists of the application of energy from the infrared, visible, or ultraviolet spectrum to the wound site to promote healing (MACHADO, 2017). Low-level laser therapy (LLLT) consists of amplified light of low radiation power capable of promoting biochemical, bioelectric, and bioenergetic effects resulting in stimulation of microcirculation, analgesia, anti-inflammatory and anti-edematous effects, and healing.

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The use of LLLT turns on a spreading range of growth, increasing epithelial cell motility, and collagen standing, which is directly connected to the healing of PU. These insights depend on the kind of protocol (wave- length, energy amount, frequency, and power) used (MACHADO, 2017). There are several alternative names for the topical negative pressure (TNP) technique, such as: sub atmospheric pressure, sealed surface wound suction, vacuum sealing, foam suction dressing, or vacuum assisted closure (VAC). The technique generally entails putting a dressing into the wound cavity, connecting the dressing to a vacuum pump, and sealing the area with an adhesive film (Ubbink, 2009). Vacuum assisted closure (V.A.C) therapy is indicated for the treatment of grade 3 and 4 pressure ulcers when conventional treatment has failed or when more rapid progress is needed to achieve the required aims of wound bed preparation or exudate management (Banwell, 2006). An accurate and thorough wound assessment is an essential component of optimal wound care. A wound assessment serves two important purposes to determine wound severity in order to predict expected rate of wound healing and develop a comprehensive plan of care and to act as a reliable outcome measure that can be used to assess the effectiveness of a given wound treatment program. A key parameter that should be included in a wound assessment is the measurement of wound extent (Houghton, 2000). Dimensional assessment: Measuring wound area or wound volume over time can be a useful way to document single or multiple patient outcomes. The trend toward healing, however, can be discerned only by comparing observations over time (Goldman, 2002). Pressure ulcers are associated with ill health and poor mobility. They are a considerable healthcare problem worldwide in relation to the detrimental effect they have on the patients' quality of life, as well as the burden to healthcare organizations, the impact pressure ulcers have from both a quality of life and a financial perspective is influenced by their severity (Coleman, 2014). This study was developed to compare between effects of low-level laser therapy versus Vacuum assisted closure therapy in treating pressure ulcers, and was designed to provide a guideline about the effect of LLLT and VAC application on acceleration of wound healing and to assist in planning an optimal and ideal treatment protocol for wound healing acceleration.

MATERIALS AND METHODS

Subjects: Forty-five patients were diagnosed by a physician as pressure ulcer patients participated in this study. Their ages were ranged from 45 to 65 years. The participants were selected from El Kasr El Aini hospital and randomly distributed into three groups of equal number. Patients were enrolled in the trial if they met the following criteria :(1) Both sexes age ranged between 45 - 65 years (2) Pressure ulcers; Grade II or III according to European Pressure Ulcer Advisory Panel Grading System 2014, (3) Free from immune deficiency diseases as well as collagen disease, (5) Free from blood clotting disorders as hemophilia. The exclusion criteria were: (1) Patients was suffering from diabetes, (2) Patients with malignancies or receiving radiotherapy or chemotherapy, (3) Necrotic tissue with eschar, (4) Fistula to an organ or body cavity within the vicinity of the wound, (5) Patients with life threatening disorders as myocardial infarction, (6) Recent therapy with immunosuppressant or anticonvulsant drugs, (7) Concurrent participation in another clinical study, (8) Patients suffering from psychological problems.

Design of the study: All aspects of the study were disclosed and informed consent was obtained. This trial was a randomized experimental study and was assented by the Ethical Committee of the Faculty of Physical Therapy, Cairo University. The current study was conducted during a period of 4 months starting from 1st March 2021 till 30th June 2021. The patients were randomly assigned into three equal groups via the envelope mode. After patients' agreement to participate in the study, cards with "Low-level laser therapy", "Negative pressure therapy" and "regular pressure ulcer care" recorded on them were closed in envelopes; then a blinded physical therapist was asked to select one envelope. According to the selected card, patients were assigned to their corresponding group. Dates for starting the allocated therapy were regulated and the therapy was begun after the first week of randomization. The examiner physical therapist was not included in randomization procedures and was unaware of the therapy allocation. Patients were asked not to disclose their therapy allocation to the physical therapist during assessment. The participants were informed to report any harmful effects throughout the treatment period.

Equipment

Measurement equipment

Wound Desk: Smart app for wound measurement, assessment, and management. Wound Desk is a tool to be used solely by health care professionals. The application can help in keeping track of all patients and their chronic wounds, by offering a place for documentation but also tools such as semi-automated wound surface measurements (NILSSON).

Ulcer volume measurement (UVM): The volume was measured by injecting a sterile gel into the ulcer cavity.

Therapeutic equipment:

Low level laser Therapy (LLLT) Infrared laser (gallium-aluminum-arsenide) with wavelength 850 nm with a power output 50 MW, (Chattanooga 2779 Intellect® Advanced Mobile Laser, made in MEXICO) was used in this study

Vacuum assisted closure therapy (VAC): Negative pressure wound therapy that was used in this study is (RENASYS EZ PLUS, a suction device with maximum negative pressure - 200mmHg, model: REF 66800697 and made in USA).

Procedures of the study

Evaluation procedures: The evaluation was conducted before the beginning of treatment and after 4 weeks of treatment.

Ulcer surface area (USA) measurement: The ulcer surface area was measured according to the following steps: A standard metering sheet was placed on the side of the ulcer defined by the Wound Desk App, and taking a digital image with a 64-megapixel mobile camera via a smart mobile app Digital MedLab's Wound Desk that processes the image and determines the surface area accurately.

Ulcer volume measurement (UVM): The measurements of volume of the ulcer was conducted according to the following steps: The sore was prepared so that the surrounding skin is clean and dry.

A transparent adhesive was applied tightly over the sore and surrounding skin, the film was extended sufficiently beyond the same margin to ensure good adhesion. The ulcer then was filled with sterile gel by injection through the film. The gel size required to fill the ulcer cavity was recorded.

Therapeutic procedures

(LLLT group): Non-contact technique of laser application was used with the laser probe perpendicular 2 millimeters away from the ulcer surface, treating the ulcer according to the grid technique 90 seconds for every centimeter square of the ulcer surface with 10 minutes as the total time of the session. Sessions was applied 3 times per week.

VAC group: In this group, the treatment procedures were conducted daily for 4 weeks through the following technical steps:

Patients received Vacuum assisted closure therapy: Initial cycle; continuous mode for first 2 days. Subsequent cycle; intermittent mode (5min. ON: 2min. OFF); Target pressure; -125mmHg; Polyurethane ether foam with pore size is approximately 400- 600 μ m, the foam was cut to precisely fit the selected wound; An evacuation tube with side ports, which communicates with the foam, and embedded in it; An adhesive tape to apply over the area with an additional 5cm border of intact skin to provide an intact seal; Canister collects the effluent from the wound and Dressing changes interval; every 48 – 72 hours, not less than 3 times per week (Mendez-Eastman, 2001).

Statistical procedures

Data Analysis: Descriptive statistics and ANOVA test were conducted for comparison of age between groups. Chi-squared test was used for comparison of sex distribution between groups. Normal distribution of data was checked using the Shapiro-Wilk test for all variables. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. One way MANOVA was performed to compare between groups effects on ulcer surface area and volume. Post-hoc tests using the Tukey test were carried out for subsequent multiple comparison. Paired t test was performed for comparison between pre and post treatment in each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

RESULTS

Subject characteristics: Table (1) showed the subject characteristics of the group A, B and C. There was no significant difference between groups in age and sex distribution ($p > 0.05$).

Effect of treatment on ulcer surface area and volume:

Within group comparison: Within-group comparison revealed a significant decrease in ulcer surface area and volume in the three groups post treatment compared with that pre treatment ($p < 0.001$). The percent of decrease in ulcer surface area and volume in the group A was 21.46 and 33.58%

respectively and that of group B was 37.24 and 43.9% respectively while that of group C was 9.45 and 22.77% respectively. (Table 2) (Fig: 1 ,2 ,3)



Fig 1. Pre and post application of VAC for pressure ulcer



Fig 2. Pre and post application of LLLT for pressure ulcer





Fig. 3. Pre and post application of traditional medical care for pressure

Between group comparison: Between groups comparisons pretreatment revealed a no significant difference in all parameters ($p > 0.05$). Comparison between groups post treatment revealed a significant decrease in ulcer surface area and volume of group B compared with that of group A ($p < 0.01$) and group C ($p < 0.001$). Also, there was a significant decrease in ulcer surface area and volume of group A compared with that of group C post treatment ($p < 0.001$). (Table 2).

9.45% , and 22.7% respectively. Numerous case reports and clinical trials with humans have shown impressive wound healing outcomes using LLLT.¹² Further work with animals has also supported the use of LLLT to facilitate wound healing.¹³ Conversely, several studies or groups have shown no advantage in healing with LLLT.¹⁴ , however this study reported improvement in both wound volume and surface area in response to laser , the possible explanation may be due to the effects of LLLT in each phase of wound healing, as LLLT activates lymphocytes and monocytes, and increases phagocytotic capacity of neutrophils, and increases the release of growth factors. Also, neovascularization is enhanced by photo-stimulation of endothelial cells, moreover LLLT increases proliferation of fibroblasts and keratinocytes, as well as collagen synthesis and deposition that contribute towards granulation tissue formation and epithelialization (Pinheiro, 2005).

On the other hand, regarding to NPWT, Kayala et al. (2019) reported that NPWT produced significant improvement in wound depth and surface area ($p < 0.05$) in patient with bedsores when they compared NPWT with traditional gauze dressings, as the average depth of ulcer pretreatment was 8mm and 7.1 mm respectively and changed to 1.8 mm and 5.4mm respectively following treatment, while average size of the ulcer was 9.2cm² and 8.6cm² respectively and changed to

Table 1. Basic characteristics of participants

	Group A	Group B	Group C	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age (years)	55.8 ± 6.8	56.66 ± 4.93	54.73 ± 5.65	0.66
Sex, n (%)				
Females	7 (47%)	6 (40%)	9 (60%)	0.53
Males	8 (53%)	9 (60%)	6 (40%)	

SD, standard deviation; p-value, level of significance

Table 2. Mean ulcer surface area and volume pre and post treatment of group A, B and C

	Group A	Group B	Group C	p-value		
	mean ± SD	mean ± SD	mean ± SD	A vs B	A vs C	B vs C
<i>Ulcer surface area (cm²)</i>						
Pre treatment	92.81 ± 8.51	97.38 ± 7.99	93.98 ± 10.32	0.35	0.93	0.56
Post treatment	72.89 ± 5.55	61.12 ± 6.59	85.1 ± 7.75	0.001	0.001	0.001
MD	19.92	36.26	8.88			
% of change	21.46	37.24	9.45			
t- value	8.92	23.37	7.8			
	$p = 0.001$	$p = 0.001$	$p = 0.001$			
<i>Ulcer volume (ml)</i>						
Pre treatment	219.84 ± 24.39	223.83 ± 20.37	225.16 ± 18.26	0.86	0.77	0.98
Post treatment	146.02 ± 21.91	125.57 ± 19.91	173.88 ± 16.77	0.01	0.001	0.001
MD	73.82	98.26	51.28			
% of change	33.58	43.9	22.77			
t- value	11.65	12.7	3.73			
	$p = 0.001$	$p = 0.001$	$p = 0.001$			

SD, Standard deviation; MD, Mean difference; p-value, Level of significance

DISCUSSION

The purpose of this study was to investigate the effect of negative pressure versus low level laser therapy on healing of pressure ulcers. The results showed significant decrease in wound surface area and wound volume in all groups ($p < 0.001$). However higher statistical results were achieved in NPWT group, as wound surface area and volume decreased in NPWT group by 37.24%, and 43.9% respectively while in LLLT group decreased by 21.46% and 33.58% respectively, on the other side the control group exhibits reduction only by

2.4cm² and 5.8cm² respectively following treatment. They concluded that NPWT is an effective method in the management of bedsores, also Boone et al. (2010) reported that NPWT produced improvements in local wound appearance. This occurred despite a persistently high level of bacterial infection; thus, the improvement in healing of these infected wounds can be explained by a change in the bacterial burden. Siddha et al., 2015 compared between NPWT and conventional dressing in one hundred patients with ulcers and reported 29.72% decrease in wound area in the NPWT group compared to 19.97% decrease in conventional dressing with P

= 0.000. In wound scoring, 68.16% improvement was seen in the NPWT group as compared with 57.10% in the control group with $P = 0.002$. There is 19.41% decreased duration of hospital stay in the NPWT group. There was a significant decrease in wound infection clearance of 63.4% in the NPWT group as compared to 34% in the control group with $P = 0.005$. In a similar comparative study by Tauro et al., 2007 who evaluated the rate of granulation tissue formation in 112 patients with chronic wounds after 10 days of treatment which was 71.43% of ulcer surface area in the NPWT group compared to 52.85% in the conventional dressing group, while the mean graft take-up was 79.29% and 60.45% respectively, and the mean hospital stay was 32.64, and 60.45 days respectively. The study concluded that NPWT helps in faster healing of chronic wounds and better graft take-up and reduce hospital stay of these patients. Another similar comparative study conducted by Dwivedi et al 2016, who evaluated NPWT in traumatic paraplegia patients with sacral pressure ulcers, there was decrease in ulcer Length and width ($p < 0.01$) in NPWT group compared to conventional dressing group at week 9, with a significant reduction of ulcer depth ($p = 0.01$) in NPWT group, also exudates were significantly ($p = 0.001$) lower at weeks 4 and 9. Conversion of slough into red granulation tissue was significantly higher ($p = 0.001$). Discharge became significantly ($p = 0.001$) lower at week 2 and no discharge was observed after week 6. In all parameters, decrease was larger in NPWT group compared with standard care, which was significant for exudates type ($p = 0.03$) and tissue type ($p = 0.004$).

From all the previous studies, it was concluded that NPWT has a prominent role and significant effect in pressure ulcer management, the possible explanation for these significant results is the various mechanisms by which the negative suction dressings act through reduction of bacterial burden and chronic interstitial wound fluid, increasing vascularity, induction of wound contraction, promotion of granulation and angiogenesis, and cytokine expression and to an extent mechanically exploiting the viscoelasticity of peri wound tissues (Hasan et al., 2015). Another possible explanation may be due to the daily use of NPWT which could provide more improvement rather than LLLT which was applied 3 times per week. This study was limited by a small sample size, psychological status of the patients that might have affected the treatment programs and evaluating procedures, individual differences in patients' response to pressure ulcer healing. More studies should be conducted to show the impact of different types of laser on pressure ulcers, more extensive studies with larger sample size are needed to ensure the role of negative pressure wound therapy and low level laser therapy in management of different pressure ulcers, further studies are needed to compare different approaches in the management and closure of pressure ulcers.

Conclusion

Both negative pressure therapy and low-level laser therapy had a positive effect on pressure ulcers healing, however, negative pressure therapy was more significant in reducing ulcer surface area and ulcer volume. No side effects were reported during the treated so both modalities were safe. Negative pressure wound therapy is a safe method and had more significant effect on pressure ulcers healing than low level laser therapy.

Conflict of interest: There is no conflict of interest.

Source of funding: None.

List of Abbreviation

LLLT	low-level laser therapy
TNP	topical negative pressure
VAC	vacuum assisted closure
USA	Ulcer surface area
UVM	Ulcer volume measurement
PU	pressure ulcer
NPWT	Negative pressure wound therapy
NPUAP	National Pressure Ulcer Advisory Panel

REFERENCES

- Grey, J.E., Enoch, S. and Harding, K.G. 2006 Pressure ulcers. *BMJ* 332 (2006), 233–252.
- Muntlin Athlin, Å., Engström, M., Gunningberg, L. and Bååth, C. 2016 Heel pressure ulcer, prevention and predictors during the care delivery chain - when and where to take action? A descriptive and explorative study. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine* 24 (2016), 1–7.
- 3-Smith, M.E.B., Totten, A., Hickam, D.H., Fu, R., Wasson, N., Rahman, B., et al. 2013 Pressure Ulcer Treatment Strategies. *Annals of Internal Medicine* 159 (2013), 39–50.
- MACHADO, R.S., VIANA, S. and SBRUZZI, G. 2017 Low-level laser therapy in the treatment of pressure ulcers: systematic review. *Lasers Med Sci* 32 (2017), 937–944.
- Ubbink, D.T., Westerbos, S.J., Evans, D., Land, L. and Vermeulen, H. 2009 Topical negative pressure for treating chronic wounds. *Cochrane Database of Systematic Reviews* (2009), 1–34.
- Banwell, P.E. and Harding, K. 2006 VACUUM ASSISTED CLOSURE THERAPY SCIENCE & PRACTICE, *Medical Education Partnership Ltd.*
- Houghton, P.E., Kincaid, C.B., Campbell, K.E., Woodbury, M.G. and Keast, D.H. 2000 Photographic assessment of the appearance of chronic pressure and leg ulcers. *Ostomy/wound management* 46 (2000), 20–30.
- Goldman, Robert J., R.S. 2002 Extra Wound Measurement. *Advances in Skin and Wound care* 15 (2002), 236–246.
- Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., et al. 2014 A new pressure ulcer conceptual framework. *Journal of Advanced Nursing* 70 (2014), 2222–2234.
- NILSSON, C.A. and Velic, M. 2018 *Classification of fashion article images using n, Chconvolutional neural networks.*
- Mendez-Eastman, S. 2001 Guidelines for using negative pressure wound therapy. *Advances in skin & wound care* 14 (2001), 314–323.
- Nussbaum EL, Biemann I, Mustard B. Comparison of ultrasound/ultraviolet-C and laser for treatment of pressure ulcers in patients with spinal cord injury. *Phys Ther.* 1994; 74(9) : 812 -23
- Kazemi-Khoo N. Successful treatment of diabetic foot ulcers with low-level laser therapy. *The Foot.* 2006,16(4) : 184 -7.
- Moshkovska T, Mayberry J. It is time to test low level laser therapy in Great Britain. *Postgrad Med J.* 2005; 81(957) : 436 -41.
- Pinheiro, A. L. B., Pozza, D. H., Oliveira, M. G. D., Weissmann, R., and Ramalho, L. M. P. (2005): Polarized light (400–2000 nm) and non-ablative laser (685 nm): a description of the wound healing process using

- immunohistochemical analysis. *Photomedicine and Laser Therapy*, 23(5), 485-492.
- Kayala, R., Manasa, K. V., and Reddy, M. (2019): Efficacy of negative pressure wound therapy when compared to gauze dressings in the management of bedsores. *International Journal of Surgery*, 3(4).
- Boone, D., Braitman, E., Gentic, C., Afthinos, J., Latif, J., Sordillo, E., and Lantis II, J. C. (2010): Bacterial burden and wound outcomes as influenced by negative pressure wound therapy. *Wounds*, 22(2), 32.
- Siddha, L.V., Shetty, S.K. and Varghese, T. (2015) Efficacy of Modified Vacuum Assisted Closure in Wound Healing. *International Journal of Scientific Study* 2 (2015), 52–59.
- Tauro L, Jayakumar R, Rao BS, Shenoy H, Shetty SR. A comparative study of the efficacy of topical negative pressure moist dressings and conventional moist dressings in chronic wounds. *Indian January Journal of Plastic Surgery*; 2007: 40(2):133-140.
- Dwivedi MK, Srivastava RN, Bhagat AK, Agarwal R, Baghel K, Jain A, Raj S. Pressure ulcer management in paraplegic patients with a novel negative pressure device: a randomised controlled trial. *J Wound Care*. 2016;25:199–200, 2-4, 6-7.
- Hasan, M. Y., Teo, R., and Nather, A. (2015). Negative-pressure wound therapy for management of diabetic foot wounds: a review of the mechanism of action, clinical applications, and recent developments *Diabetic foot & ankle*, 6(1), 27618.
